IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

NADINE AVICOLLI, *et al.*	:	**CIVIL ACTION**
	:	
v.	:	**NO. 21-1119**
	:	
BJ'S WHOLESALE CLUB, INC., *et al.*	:	

MEMORANDUM

KEARNEY, J. **April 7, 2021**

Consumers claiming harm from ingesting hand sanitizers following the onset of the COVID pandemic may sue the sanitizer's manufacturer and retailer for product defect or negligence. They must do so aware Congress afforded immunity from liability to certain retailers qualified under a fifteen-year-old federal law and present Declaration from the Secretary of Health and Human Services which, among other qualifies, defines the method of distribution responsive to a defined health risk which may afford immunity for a retailer. Not every retailer of hand sanitizer is covered under the limited immunity. The consumers do not necessarily know if the retailer obtained the hand sanitizer for re-sale before the pandemic or to assist in mitigating the spread of the pandemic. The allegedly injured consumer can generally plead only the purchase and resulting harm. We are mindful immunity both frustrates recovery from possibly responsible parties but also incentivizes manufacturers and sellers to create and market products which the Government approves to mitigate the pandemic. But we cannot grant immunity from liability and summarily dismiss a complaint based on the face of the consumer's allegations which do not allow us to find the retailer obtained the hand sanitizer in response to the pandemic or under specific distribution channels directed by the Secretary. We must accordingly deny the retailer's motion to dismiss claims against it subject to discovery and further evaluation of whether the immunity to liability defense afforded by Congress and implemented by the Secretary may apply.

I. Alleged Facts

Pennsylvanian Dennis Avicolli purchased a seventeen-ounce bottle of Blumen Clear Advanced Hand Sanitizer from a BJ's Wholesale Club in May 2020.[1] The manufacturer of the hand sanitizer recalled all of its seventeen-ounce bottles two months later, including the bottle purchased by Mr. Avicolli, because it contained methanol or wood alcohol.[2] BJ's subsequently issued a press release regarding the recall.[3] Mr. Avicolli's wife Nadine Avicolli ingested some of the hand sanitizer in August 2020.[4] Mrs. Avicolli experienced, among other things, "a great deal of weakness on the left side of her body as well as a substantial loss of her vision."[5] The Avicollis did not know of the recall.[6]

The Avicollis sued BJ's and the international manufacturer and regional distributor of the hand sanitizer broadly alleging product defect, lack of warning labels, and negligence.[7] The Avicollis seek damages arising from BJ's:

- Fail[ing] to distribute, market and sell the Blumen Clear Advanced Hand Sanitizer with adequate safety features to protect persons using the product;
- Fail[ing] to distribute, market and sell the Blumen Clear Advanced Hand Sanitizer with adequate provisions and/or components to prevent foreseeable harm;

…

- Distributing, marketing, and selling a product with a label that its active ingredient is seventy percent (70%) ethyl alcohol without any mention of the presence of methanol (wood alcohol);
- Distributing, marketing, and selling a product with a label that it contains seventy percent (70%) alcohol;

- Distributing, marketing, and selling a product without warning of the hazards of ingesting its alcohol-based product;

- Distributing, marketing, and selling a product containing methanol (wood alcohol) without warning of the hazards of ingesting methanol (wood alcohol);

…

- Allowing a condition to exist that could and did cause the Blumen Clear Advanced Hand Sanitizer to cause serious bodily injury;

- Selling a product which had the propensity and capability to harm those that come into contact with it;

- Failing to distribute a product with adequate safety features; [and]

- Failing to market a product with adequate safety features[.][8]

II. Analysis

BJ's moves to dismiss the claims arguing (1) immunity from liability under the Public Readiness and Emergency Preparedness Act[9]; (2) the Avicollis do not allege willful misconduct by BJ's, which is the sole exception to immunity under the Act; and (3) the Avicollis failed to exhaust administrative remedies required by the Act.[10] BJ's request we transfer this action to the United States District Court for the District of Columbia because the Act vests exclusive jurisdiction there for actions involving allegations of willful misconduct against entities covered by the Act.[11] The Avicollis argue the Act does not apply because Blumen hand sanitizer does not qualify as a "covered countermeasure" under the Act.[12]

In determining whether to grant a 12(b)(6) motion, "we accept all well-pleaded allegations as true and draw all reasonable inferences in favor of the plaintiff" but "disregard threadbare recitals of the elements of a cause of action, legal conclusions, and conclusory statements."[13]Our

Court of Appeals requires us to apply a three-step analysis under a 12(b)(6) motion: (1) "it must 'tak[e] note of the elements [the] plaintiff must plead to state a claim;'" (2) "it should identify allegations that, 'because they are no more than conclusions, are not entitled to the assumption of truth;'" and, (3) "[w]hen there are well-pleaded factual allegations, [the] court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief."[14]

While immunity serves as an affirmative defense, we may dismiss under Rule 12(b)(6) where the affirmative defense appears on its face.[15] Immunity, therefore, "'will be upheld on a 12(b)(6) motion only when the immunity is established on the face of the complaint.'"[16]

The threshold question we must therefore consider is whether – based solely on the Avicollis' allegations – the claims against BJ's fall within the scope of liability immunity under the Act. We conclude they do not. We deny the Motion to dismiss and to transfer venue as the Act does not apply based on the Avicollis' allegations.

We have no basis to infer BJ's obtained the hand sanitizer through the means of distribution specified by the Secretary of Health and Human Services.

BJ's assumes Congress afforded it immunity because the Act applies. Congress authorized the Secretary of Health and Human Services – in the event of a public health emergency – to issue a declaration in the Federal Register immunizing from liability certain "covered persons" from "all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration…has been issued with respect to such countermeasure."[17] Congress defines various terms to determine the scope of immunity, including:

- **Covered Countermeasure -**
  - a qualified pandemic or epidemic product (as defined in paragraph (7));
  - a security countermeasure (as defined in section 247d-6b(c)(1)(B) of this title);

  - a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(g)(1)), biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act; or
  - a respiratory protective device that is approved by the National Institute for Occupational Safety and Health…

- **Covered person** – "…a person or entity that is…a distributor of such countermeasure"

- **Distributor** – "a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies."

- **Qualified pandemic or epidemic product** – "a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is… a product manufactured, used, designed, developed, modified, licensed, or procured…to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or to limit the harm such pandemic or epidemic might otherwise cause[.]"[18]

Congress further directs the Secretary "shall identify" in his declaration various limits to immunity for each covered countermeasure identified in the declaration, including the category or categories of diseases for which the Secretary recommends the administration or use of the countermeasure and the time period(s), population(s) of individuals, and geographic area(s) for which immunity is available.[19] Congress also directs the Secretary to identify whether immunity "is effective only to a particular means of distribution…for obtaining the countermeasure, and if so, the particular means to which such subsection is effective."[20]

COVID-19 became a United States health crisis in early 2020. In March 2020, Secretary Alex M. Azar II issued a Declaration under the Act in response to the COVID-19 pandemic.[21]

Consistent with his authority under the Act, Secretary Azar limited immunity "only to Covered Countermeasures obtained through a particular means of distribution."[22] The Secretary specifically limited liability for "Covered Persons for [the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures] related to (a) present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements; or (b) activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures following a Declaration of an emergency."[23]

Our Court of Appeals instructs "[w]hen interpreting a statute, 'our task is to give effect to the will of Congress, and where Congress's will has been expressed in language that has a reasonably plain meaning, that language must ordinarily be regarded as conclusive.'"[24] When, however, statutory language is not plain and unambiguous, we must consider statutory language "in the larger context or structure of the statute in which it is found."[25] There exists little case law interpreting the Declaration due to its relative recency. The Office of the General Counsel for the Department of Health and Human Services, however, issued an advisory opinion explaining various portions of the Declaration.[26] With respect to the Secretary's limitations to particular means of distribution, the Office of General Counsel explained "w[e] interpret these two conditions broadly to include (1) any arrangement with the federal government, or (2) any activity that is part of an authorized emergency response at the federal, regional, state, or local level. Such activities can be authorized through, among other things, guidance, requests for assistance, agreements, or other arrangements."[27]

BJ's argues Congress immunizes it from liability to the Avicollis because (1) it is a "covered person" as a "distributor"; (2) hand sanitizer is "covered countermeasure" because it is a "qualified pandemic or epidemic product"; and (3) the claims arise from the "administration or use" of the hand sanitizer. It does not, however, mention immunity is restricted to covered countermeasures obtained through a particular means of distribution.

We need not decide whether BJ's, the hand sanitizer, and the Avicollis' claims fit within the Act's coverage because the Avicollis do not allege – nor does BJ's provide a basis for us to infer – BJ's obtained the hand sanitizer through one of the two means of distribution specified by the Secretary. The Avicollis do not allege BJ's obtained this hand sanitizer under agreement with the federal government or in response to the COVID-19 pandemic.

These facts are distinguishable from, for example, a distillery which began obtaining and selling hand sanitizer as part of a coordinated effort to mitigate the spread of COVID-19. The Avicollis' allegations can be plausibly read to infer BJ's obtained and sold this hand sanitizer before COVID-19. There is no basis to infer BJ's obtained the hand sanitizer through the distribution channels necessary to qualify for immunity from liability.

We cannot find Congress extended immunity through the Secretary to BJ's for the sale of this hand sanitizer given the deference we must afford the allegations at this stage. We have no basis from the face of the Avicollis' allegations to conclude the Act affords BJ's immunity from liability from the Avicollis' claims. We need not address BJ's remaining arguments regarding willful misconduct and transfer of venue as the Act does not apply based solely on the allegations. The parties may proceed into discovery which may adduce facts warranting an immunity finding.

III. Conclusion

We deny BJ's Motion to dismiss or to transfer venue.

[1] ECF Doc. No. 1-1 ¶ 15.

[2] *Id.* ¶¶ 18, 20.

[3] *Id.* ¶¶ 23, 25.

[4] *Id.* ¶ 31.

[5] *Id.* ¶ 32.

[6] *Id.* ¶¶ 18, 24.

[7] See generally ECF Doc. No. 1-1. We dismissed the store manager in our March 22,2021 Order. ECF Doc. No. 11. The Avicollis have not confirmed service upon the international manufacturer or distributor.

[8] ECF Doc. No. 1-1 ¶ 60.

[9] 42 U.S.C. §§ 247d 6d, 247d-6e (2006).

[10] ECF Doc. No. 5-1.

[11] *Id.* at 8.

[12] ECF Doc. No. 12-2 at 7-11.

[13] *Robert W. Mauthe M.D., P.C. v. Spreemo, Inc.*, 806 F. App'x 151, 152 (3d Cir. 2020) (quoting *City of Cambridge Ret. Sys. v. Altisource Asset Mgmt. Corp.*, 908 F.3d 872, 878-79 (3d Cir. 2018)).

[14] *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 787 (3d Cir. 2016) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675, 679 (2009)).

[15] *Allstate Vehicle and Prop. Ins. Co. v. Phila. Housing Auth.*, 394 F. Supp. 3d 535, 538-39 (E.D. Pa. 2019) (citing *Leveto v. Lapina*, 258 F.3d 156, 161 (3d Cir. 2001)).

[16] *Id.* at 539 (quoting *Leveto*, 258 F.3d at 161); *see also Phillips v. Rustin*, No. 06-1338, 2007 WL 2823334, at *1 (W.D. Pa. Sept. 26, 2007) (denying motion to dismiss based on statutory immunity "[b]ecause the crucial analysis of immunity under the [act] requires development of a factual record beyond what is alleged in the complaint"); *Alexander v. Hackensack Meridian Health*, No. 19-18287, 2020 WL 5810526, at *9 (D.N.J. Sept. 30, 2020) (declining to dismiss claims based on statutory immunity because at this early stage, "the [c]ourt evaluates whether, accepting [p]laintiffs' allegations as true, [d]efendants would be entitled to immunity under the [acts]" and plaintiffs plausibly alleged the defendants were not entitled to immunity).

[17] 42 U.S.C. § 247d-6d(a)(1).

[18] *Id.* at (i)(1)-(3), (7).

[19] *Id.* at (b)(2)(A)-(D).

[20] *Id.* at (b)(2)(E).

[21] 85 Fed. Reg. 15198-01.

[22] *Id.* at § 7.

[23] *Id.*

[24] *United States v. Medco Health Solutions, Inc.*, 880 F.3d 89, 95 (3d Cir. 2018) (quoting *Byrd v. Shannon*, 715 F.3d 117, 122 (3d Cir. 2013)).

[25] *Id.* (quoting *United States v. Tupone*, 442 F.3d 145, 151 (3d Cir. 2006)).

[26] Department of Health & Human Services, Office of the General Counsel, *Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under the Act* (April 17, 2020, modified on May 19, 2020).

We construe the Declaration consistent with the advisory opinion, remaining mindful the advisory opinion "does not have the force or effect of law." *Id.*

[27] *Id.* at 2.